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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,700	01/09/2003	Robert Paul Anderson	HO-P02416USO	2705

34141 7590 05/14/2004

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,700	ANDERSON ET AL.	
	Examiner	Art Unit	
	David A Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *60-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment of 4/1/02 has been entered. Claims 60-111 are pending and subject to restriction, as stated further infra.

To clarify the record it is deemed that claims 60-111 correspond to original claims 1-59 as follows:

Pending claim(s)	original claim(s)
60	1
61-62	3-4
63	6
64	5
65-71	7-13
72-80	16-24
81-82	25
83-84	26
85-86	27-28
87-88	41-42
89-91	37-39
92-97	31-36
98-104	45-51
105	52-53
106-111	54-59

Also, for clarification of the record, it is to be noted that the IPEA withdrew claims pertaining to diagnostic or therapeutic processes performed upon a human or animal body. Therefore this present restriction will include more groups than those listed by the IPEA.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 60-69, 71, 88, drawn to methods of diagnosing coeliac disease.

Group II, claim(s) 70, drawn to methods of identifying T-cell receptor binding analogues.

Group III, claim(s) 72, 87 (1st alternative), drawn to body treatments using eptitopic analogues.

Group IV, claim(s) 73-74, drawn to methods of determining the presence of allergenic proteins in a composition.

Group V, claim(s) 75, drawn to mutant gliadin proteins.

Group VI, claim(s) 76, drawn to antagonists (e.g. protein segments) that bind T-cell receptors.

Group VII, claim(s) 77, drawn to methods of identifying T-cell antagonists.

Group VIII, claim(s) 78-80, drawn to kits with reagents to detect T-cell recognition of peptides.

Group IX, claim(s) 81, 83, 85, drawn to peptides/analogues of gliadin epitopes.

Group X, claim(s) 82, 84, 86, drawn to antagonists of T-cells.

Group XI, claim(s) 87 (2nd alternative), drawn to body treatments using T-cell antagonists.

Group XII, claim(s) 89, drawn to mammals expressing a T-cell receptor recognizing gliadin epitopes.

Group XIII, claim(s) 90-91, drawn to methods of identifying therapeutic products for treating celiac disease.

Group XIV, claim(s) 92 (part a)-98, drawn to polynucleotides encoding mutant gliadin, expression vectors, transformal cells, and processes of producing protein from such cells.

Group XV, claim(s) 92 (part b)-98, drawn to polynucleotides encoding antagonist peptide epitopes, expression vectors, transformed cells, and processes of producing protein from such cells.

Group XVI, claim(s) 99-106, drawn to methods of obtaining transgenic plants and plant products thereof.

Group XVII, claim(s) 107-111, drawn to methods of processing plant products and foods obtained.

The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 requires that applicant provide a special technical feature which defines a contribution over the prior art, in order to provide for unity of invention.

As noted by the IPEA, applicant has not provided such a feature which defines over the prior art.

Regarding claim 60 of Group I, the IPEA has noted four documents which anticipate original claim 1(separate sheets 2-3). Claims of Group I thus do not provide a feature which defines over the prior art.

With respect to claim 70 of Group II, the IPEA has cited five documents which anticipate original claim 12 (separate sheets 4-5). Claims of Group II thus do not define over the prior art.

Regarding claim 70 (Group II) and 73 (Group IV), the subject matter of which the IPEA apparently Grouped with the diagnostic methods of Group I, it is to be noted that the IPEA considered the subject matter of all dependent diagnostic claims as providing no inventive step over the prior art (separate sheet 3).

With respect to claims 78-80 (Group VIII) the present examiner notes that these kits provide no contribution over the prior art, since kits for the detection of T-cell activation (e.g. via radioactive thymidine incorporation, or via detection of secreted cytokines/lymphokines) are old and can be used to detect T-cells sensitized against any peptide. There is thus no contributing feature that provides a nexus between the kits of claims 78-80 and the peptides of claim 1.

Regarding claim 81 (Group IX), it is noted that base claim 60 recites "comprising", which is open language with respect to each recited sequence. Claim 81 thus encompasses the whole gliadin protein and is not novel.

Regarding claim 82 (Group X) the present examiner notes that this encompasses any conventional antagonist of T-cells and as such does not define over

the prior art. It is also noted that, since such antagonists would suppress the responsiveness of any T-cell, irrespective of the specificity of its T-cell receptor, there is no defining nexus between the antagonist of claim 82 and the peptides of base claim 60.

With respect to claim 87 (Group XI), this encompasses a body treatment with any conventional antagonist of T-cells, irrespective of their T-cell receptor binding specificity. As such this claim does not define over the prior art and has no nexus with the peptides of base claim 60.

Regarding claim 89 (Group XII), this encompasses any mammal which inherently had T-cells recognizing the peptides of claim 60. The claim provides no contribution over the prior art, since humans throughout history who have been allergic to gliadin are within the scope of the claim.

With respect to claim 90 (Group XIII), this merely involves administering a test substance to a patient having allergy to gliadin. As noted regarding claim 89, such patients inherently have the T-cells of base claim 60. Since candidate drugs have been tried on such patients, the claim defines no contribution over the prior art.

Regarding claim 92, part a) and claim 92, part b) (Groups XIV and XV, respectively), the IPEA has found claims pertaining to the transformed cell as anticipated (separate sheet pgs. 3-4) as well as claims to polynucleotides and vectors as having no inventive step over prior art (separate sheets pgs 4-5).

Regarding claims 99-106 (Group XVI), the IPEA has found claims pertaining to the transgenic plants as lacking an inventive step (separate sheets 3-4).

With respect to claims 107-111 (Group XVII), the IPEA has found claims to food processing and products thus obtained as lacking an inventive step (separate sheet 4).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

May 10, 2004

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1624